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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,250	10/24/2003	Gene DiPoto	1291.1141101	1390
28075 7590 09/10/2007 CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420			EXAMINER MENDOZA, MICHAEL G	
			ART UNIT 3734	PAPER NUMBER
			MAIL DATE 09/10/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/693,250

Applicant(s)

DIPOTO, GENE

Examiner

Michael G. Mendoza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 6/8/2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 15-18 and 21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18 is/are allowed.
- 6) ☒ Claim(s) 1-17 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Allowable Subject Matter***

1. The indicated allowability of claim 14-17 are withdrawn in view of the newly discovered reference(s) to Ray et al. 5562736. Rejections based on the newly cited reference(s) follow.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 15-17, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bao et al. 5800549 in view of Davison 6530926 in further view of Ray et al. 5562736 and evidenced by Van Dyke et al. 6270793.
4. Bao et al. teaches a method of replacing a portion of disc of a patient, the disc having an annulus and a nucleus, comprising: advancing an annulotomy tool through an access device to the intervertebral space; forming an aperture in the annulus; advancing a disc evacuation tool through the access device and through the aperture; removing at least a portion of the nucleus through the access device to at least partially evacuate the intervertebral space; and delivering a replacement disc nucleus into the partially evacuated intervertebral space through the access device (col. 6, lines 3-18). It should be noted that Bao et al. fails to teach the access device being inserted in a first configuration having a first cross-section area at a distal portion thereof; and configuring

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the access device such that the distal portion thereof is enlarged from the first configuration to a second configuration wherein the distal portion extend across at least a portion of the disc.

5. Davison teaches a method that uses a common access having a first configuration and a second configuration for enhanced viewing of a surgical site.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the access device of Davison with the method steps taught by Bao et al. to give the surgeon performing the surgery an expanded surgery site for viewing (col. 5, lines 30-37).

6. It should also be noted that Bao/Davison fails to teach wherein the hydrogel core is surrounded by a constraining jacket, the constaining jacket being flexible but substantially inelastic.

7. Ray et al. teaches the use of a common hydrogel core is surrounded by a constraining jacket for constraining the hydrogel. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the jacket of Charles et al. with the method of Bao/Davison to allow bodily fluids to interact with the hydrogel core, and to prevent the hydrogel from escaping (col. 10, lines 7-42)

8. As to claim 15, it is well know in the art of disc replacement to use a keratin hydrogel as evidenced by Van Dyke et al. (see entire document).

***Allowable Subject Matter***

9. Claim 18 is allowable over the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 9:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



MM



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